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AGRICULTURAL RESOURCES AND THE TRIPS AGREEMENT

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Intellectual property has spread through agricultural sector influencing the characteristics of downward food sector. According to the industry, patents are a condition for conducting R&D in biotechnologies.

Since 1995, the Trade-Related Aspects of Intellectual Property Rights Agreement ("TRIPs") imposes WTO Member States minimal levels of intellectual property protection. It embraces all type of intellectual property rights and concerns many subject-matters of different kinds considered for the occasion as merchant commodities: book, film, music, software, clothing, as well as plant, DNA, chemistry, etc. In addition, for these minimal protection standards to be effective, the TRIPs Agreement requires member states to adopt enforcement measures for the rights-holders to fight against infringement. The standardization effect of those minimal intellectual property standards is reinforced by the national-treatment and the most-favoured-nation clauses, key provisions in the process of standardization of intellectual property.

As the forum for the conclusion of such Agreement, the WTO was favoured by developed countries and their industries over the World Intellectual Property Organisation of the United Nations ("WIPO"). For the developing countries, the perspective of access to the other WTO members markets was an effective incentive to accept the IP standards of the developed countries. The WTO was also favoured because of its dispute settlement mechanism. Moreover, the possibilities of trade retortion measures it offers are an effective sanction mechanism in case of non compliance with its international commitments. As a matter of fact, the standardization established by the TRIPs constitutes a key instrument for securing the exploitation of their IPR by industries of the developed countries. It is of

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common sense that the IPR-industry (chemical industry, biotech-industry, agro-industry, as well as entertainment and copyright industries) is mostly established in developed countries.

Although Intellectual property is necessary to allow the recoupment of the investment in R&D, the exclusive control it guarantees to the right-holder on a given agricultural resource might in certain cases conflict with other social or economic goals such as sustainable access to food. The TRIPs Agreement limits therefore the autonomy of the countries to decide to establish an intellectual property system or to accommodate such system to social and political concerns. Nevertheless, it must be noted that it comes out of Article 7 of the Agreement that the *objective* of the protection of intellectual property rights was considered to contribute to social and economic welfare[2]. In addition, article 8 seem to consider favourably the adoption by member states of measures necessary to protect public health and nutrition…provided however that such measures are consistent with the treaty (Article 8)[3].

1. The mandatory patent subject-matter

The most relevant intellectual property rights as to agricultural resources are the patent right and the plant variety protection system (PVP)[4]. Article 27 § 1 of TRIPs commands member states to make patent available " for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". Patent shall be available "without discrimination as to the place of invention and whether products are imported or locally produced". Therefore, member states are not allowed to exclude the life-science field, nor agricultural or food fields from patentability.

A patent gives the right-holder many "exclusive rights". The holder of the patent has the exclusive right of making, using, offering for sale, selling, or importing for these purposes,

[2] Article 7 : "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

[3] For further reflection on Article 8 as a basis to limit patentability, see the contribution of M. BLAKENEY: "Compulsory licensing and food security", see also G. VAN OVERWALLE: "Patents in Agricultural Biotechnology and the Right to Food" and H. MORTEN HAUGEN: "Research Exemptions in Patent and Plant Variety Legislation".

[4] The TRIPs Agreement also establishes minimal level of Trademark and Geographical indications protections. Although less significant for the purpose of the present report, those protection systems are also likely to have consequences on the food system.

the patented product/process or to allow others to do so. In the hypothesis of a plant-related product patent, the exclusive right may extend to the products composed of such plant and parts of plants[5].

2. Exemptions to the mandatory patent subject-matter

Article 27 states exceptions to the mandatory patentability of innovations. WTO members are allowed to exclude plants and essentially biological processes for the production of plant from patentability. Micro-organisms and microbiological processes must however be patentable. As to the plant varieties, article 27 leaves to members states the choice of the protection system to apply. Those dispositions are detailed further in this contribution.

It must be noted beforehand that TRIPs does not define any of those terms (plant, essentially biological process, micro-organisms, plant varieties) although they circumscribe the scope of the international commitments of member states as to patentability. Those terms draw the line between what is mandatorily patentable and what is not according to TRIPs. There is no scientific consensus as to definitions of those terms to refer to either. This absence of mandatory definition gives member states a breathing space when designing their national patent subject-matter[6]. Clarifications may however come out of the WTO's Dispute Settlement System, in the hypothesis of a complaint of a member as to the compliance of another member regulation to the TRIPs requirements.

[5] Concerning the application of that principle to a patent related to a DNA sequence and its important implications on the downstream food chain, see in the present report the contribution of V. CASSIERS et B. REMICHE: "Biotechnology Patent Use and Right to Food".

[6] In the E.U., some of those terms have been specified by the European Patent Office (EPO) and the European Directive 98/44 on the legal protection of biotechnological inventions (Article 53 of the European Patent Convention is almost identical to Article 27 of the TRIPs, this latter being drafted on the former's model). However, such interpretation by the EPO should not influence the interpretation of Article 27.3 (b) TRIPS. The political and economic inspirations that have determined the case-law of the EPO and the content of the European Directive on the legal protection of biotechnological inventions shall not influence the delimitation of WTO's member states international commitments concerning patentability (beside it is worth noting that the EPO case-law has lead to a gradual expansion of the scope of patentability under the EPC, notably to stick to the U.S. scope for competitiveness reasons).

2.1 Plants and essentially biological processes for the production of plants

Plants

Article 27.3 (b) exempts states from making patent available for plant. Such provision may be useful for the agricultural sector. Member states may not protect plant and its parts, or they may tailor a protection system at their discretion. According to the consultation undertaken by the Council for TRIPs[7], Argentina, Brazil, Bolivia, Canada, Colombia, Ecuador, Peru, Venezuela, and Thailand exclude plant from patentability[8] . Other member states which have answered the TRIPs Council survey generally admit the patentability of plants.

In several of the member states admitting the protection of plant[9], an adaptation of the conditions for patentability has been made (by means of a modification of the regulatory framework or as a consequence of the patent offices practice), in order to adapt them to the living material. Since patent regimes have been crafted to protect technical inventions, it makes it inappropriate to admit the patentability of biological material that occurs in nature but which was "revealed" by biotechnologies, as it appear to constitute merely discovered and not invented by human[10]. For instance the identification of a plant-related gene does not easily meet the patentability conditions of novelty, inventive step and industrial application, nor does it constitute an invention, exclusive subject-matter of patent-right. To bypass this obstacle, some states allow for patentability of biological material that has been "isolated" or "purified" from its natural environment[11]. To be adapted to biotechnologies, biological

[7] Most of the information on the national implementations of Article 27.3(b) has been taken out of the consultation undertaken by the Council for TRIPs of the WTO, which outcome has been summarized in the WTO document IP/C/W/273/Rev.1 of 18 February 2003. Information has been received from the following states: Australia, Bulgaria, Canada, the Czech Republic, the European Communities and their member States, Hungary, Japan, Korea, Morocco, New Zealand, Norway, Poland, Romania, Slovenia, South Africa, Switzerland, the United States and Zambia. Information was also found in M. TEMMERMAN: "The Patentibility of Plant GeneticInventions", available on http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1069948

[8] The lists of states contained in this contribution are illustrative and might not be exhaustive.

[9] U.S., E.U., Japan, Australia, Romania, Switzerland

[10] Traditionally, discoveries are excluded from the patent scope. Such exemption arises from a traditional conception according to which what occurs as such in the nature and is as such exempt from significant human intervention is not relevant for patentability which ambition is to protect the outcome of human inventiveness.

[11] E.g. Australia, E.U., U.S.

material produced by means of a technical process was also made patentable although previously occurring in nature [12].

In order not to be considered as mere discoveries, it is however required that an industrial application be demonstrated[13], or new or unexpected properties be exhibited[14], or the patent must not be claimed for biological material "either in the natural state, or does not encompass the plant found in its natural state"[15]. In other states, a "creative effort" is required[16] or the process used for the isolation must be new[17]. However, it is worth noting that such adaptation of the patent scope and/or conditions is not required by the TRIPs Agreement itself.

Essentially biological processes for the production of plants

The TRIPS Agreement allows for the non patentability of essentially biological processes for the production of plants as well. The E.U., Canada, Korea, Thailand and South Africa have exercised such option and exclude essentially biological processes for the production of plants from patentibility. But TRIPs does not specify the line between what is to be considered as essentially biological (and not mandatorily patentable) and what is non-essentially biological, and therefore mandatory patent subject-matter. Therefore, here also member states who choose not to patent essentially biological processes benefit from an additional margin in the designing of their patent subject-matter through the definition of those later.

Exemption to the exemption: the mandatory patentability of micro-organisms and microbiological processes

In spite of the exclusion of plant and essentially biological processes from patentability, the TRIPs Agreement makes the patentability of micro-organisms and microbiological processes mandatory. Here also, although the definition of "micro-organism" and "microbiological processes" participate to the definition of the mandatory subject-matter, they are not defined by the TRIPs and there is no unanimous scientific definition either. If biological material is qualified as micro-organism instead of plant or part of a plant, it is

[12] Article 23 (c)(a) EPC and Article 3(2) on the legal protection of biotechnological inventions.
[13] E.U.
[14] U.S.
[15] New Zealand
[16] Romania
[17] Switzerland

mandatorily patentable. Such absence of definition also provides states with additional margin in the implementation of the Agreement for those states that have excluded plants from their patent scope. For example, Brazil which excludes plant from patentability considers that it extends to parts of plant, except micro-organisms. In Thailand also, extracts of plant are not patentable in virtue of the plant exception. On the contrary, US and European patent offices have gradually qualified more types of material as micro-organisms. According to EPO, this category includes "not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells, i.e. all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory…Plasmids and viruses are also considered to fall under this definition"[18] and therefore eligible for patent protection as micro-organisms. In Brazil, some of those objects may be qualified as part of plant and therefore escape from the patentability scope.

2.2. Plant varieties: choice of the means of protection

Plant varieties are not mandatory patent subject-matter. However, member states must provide for a plant variety protection system (PVP), be the patent right, or an effective *sui generis protection, or a combination thereof.* The TRIPs does not impose any given *sui generis* protection system to be adopted by member states, not even the most well-known UPOV Breeder's Right (see below). TRIPs therefore allows member states to tailor a plant varieties protection system that balances the interest of the breeders with alternate social constraints, such as the right to food, the interest of the farmers or the protection of biodiversity. The condition however is that such system is *effective*. The Agreement does not give more details as to what is supposed to be an *effective* protection system.

The mandatory protection of plant varieties contrasts with the exemption applicable to plants. The definition of "variety" that member states will consequently adopt influences their plant intellectual property system. In states which have excluded plants from patentability, the definition of "variety" will determine what under the scope of intellectual property. In states where plants are patentable and variety are protected by a sui generis protection system, the definition of variety will determine the line between the patent right and the sui generis system.

[18] Technical Board of Appeal of the European Patent Office, *Greenpeace v. Plant Genetic System* , Case T/0356/93, 21 february 1995, § 34, available at http://legal.european-patent-office.org/dg3/pdf/t930356ex1.pdf

Most of the WTO members which have implemented the Agreement exclusively protect plant varieties with a sui generis protection system. Exceptions to this common trend are the U.S., Japan, Australia, New Zealand, Sweden and the U.K. which make patent available to plant varieties. In the U.S. and Australia, a patent protection is also available to plant varieties leaving the door open for double protection.

In spite of the discretion left to member states as to the design of a plant variety protection system of their own, one must admit that most members have chosen the UPOV protection system. Out of the 153 WTO members, around 70 are UPOV members. One reason is that many developed countries had already implemented the UPOV's Breeder's Right in their legislation before the TRIPs Agreement was concluded (see below). Other reason explaining the choice of the UPOV protection system by developing countries is the promotion of UPOV undertaken by OECD countries in their bilateral trade agreements with the former[19]. Few States have adopted an alternative (to UPOV) sui generis plant protection system: India[20], Thailand, Zambia and the African countries which have adopted the model drafted by the Organization of African Unity (Kenya, South Africa, Namibia)[21]. The U.S. has enacted its proper plant variety protection system (it has two different plant variety protection systems indeed). Amongst those alternative sui generis systems to UPOV, some are similar to this latter where others develop a significantly different approach (India and the African model).

As a conclusion, it can be stated that, generally speaking, most of the members that have implemented the Agreement have chosen to protect plant varieties with the UPOV breeder's right and do not allow for plant variety patent with the notable exception of the U.S. and Australia.

As to the possible cumulation of intellectual property rights on varieties, the following reflection must however be made. Even in states where varieties are excluded from the patent scope and may exclusively be protected by a sui generis right, one or several patents may overlap with such sui generis protection. It is common that the use and the research on a variety imply one or several patents in addition to the breeders right. The reason is that plants

[19]See in the present report the contribution of J.F. MORIN : "Intellectual Property in Agriculture and Bilateral Agreements"
[20] See the contribution of S.K. VERMA : "The TRIPs Flexibility Mechanisms and Right to Food"
[21] See the contribution of T. SANOU : "The alternative sui generis regimes as defended by the African group within the WTO: which protective system for the plant varieties?"

are at a higher taxonomy rank than varieties. As a consequence, such varieties may be concerned by plant patent(s) that are applicable to the plant of which they are a variety. Another reason is that many breeders succeed in patenting varieties thanks to the wording of their patent claim in spite of the non patentability of plant varieties. The practice of patent offices is also determining. In E.U. for instance, the European Patent Office admits the patentability of inventions that might embrace plant varieties, as long as such plant varieties are not individually claimed[22].

As it constitutes the major trend amongst WTO members which have adopted a sui generis Plant Variety Protection system, a closer look to the UPOV Breeder's Right will be useful.

The UPOV

The breeding activity got to a mature point much before biotechnologies, and from the early past century, need for protection was already expressed by the (developed countries') breeders' industry. For several reasons, patent protection was however considered inadequate. One important reason was linked to the evolving nature of living material that plants are. Given such evolving nature of plants, it was acknowledged that access to the breeding material of existent varieties had to be preserved for the development of new varieties by breeders in spite of intellectual property protection. An alternative protection system was tailored in the International Convention for the Protection of New Varieties, concluded in 1961, better known as the UPOV Convention. When the TRIPS Agreement was concluded in 1994, many States were already members of the UPOV and had integrated the Breeder's Right into their legislation. Patentability was thus not made mandatory for varieties and the choice of an *effective* sui generis protection system was left to member states. The adoption of the UPOV Breeder's Right is considered to comply with the provision of the TRIPs as to the protection of plant varieties[23] (it is also the most unanimous) although other sui generis systems may be chosen.

The original Act of the UPOV (1961) has been modified several times, the modifications tending to strengthen the Breeder's Right, making it closer to a patent system.

[22] Enlarged Board of Appeal of the EPO, *Transgenic Plant/ Novartis II*, 20 December 1999.
[23] Other sui generis protection systems are likely to satisfy to the prescription of the TRIPs concerning the protection of plant varieties.

The last version is the 1991 Act which all member states have not ratified. Consequently, the Breeder's Right does not have the same content in all UPOV members, some still applying the 1978 version.

The UPOV Breeder's Right establishes a legal protection for created or discovered plant varieties, defined as "a plant grouping within a single botanical taxon of the lowest known rank"[24], which notably presents characteristics that distinguish it from other plant groupings. Created or discovered varieties that meet the requirements of novelty, distinctiveness, stability and uniformity are eligible for protection. An authorization of the breeder of a protected variety is necessary not only for the commercialisation of the propagating material of the variety (eg. seeds, cuttings), but for its production as well[25]. However thanks to an exception, the Breeder's Right does not extend to acts done privately and for non-commercial purposes[26]. The harvested material is not concerned by the exclusive right unless it has been obtained through the unauthorized use of propagating material[27].

The UPOV Breeder's Right has been conceived more narrowly than the patent right. The Breeder's Right scope is limited to the propagating material and does not extend to harvested material[28] of a defined variety and concerns the variety *per se* and not products that are derived from the variety. It is also characterized by exemptions proper to the evolving nature of plants (the *breeder's exemption*) and is balanced according social and economic goals that may conflict with the right-holders interests (the *farmer's privilege*).

As stated above, the *breeder's exemption* constitutes one of the *raison d'être* of the Breeder's Right. The UPOV Convention recognizes the right for breeders to use protected varieties without the consent of the right-holder, in order to develop and commercialize a new variety. Although patent right may provide for research exemption, it is of limited extent and certainly does not cover the commercialization of the resulting goods[29].

The *farmers' privilege* arises from a traditional practice of the farmers of sowing and exchanging propagating material taken out of their harvest. The contribution of this practice to the development of biodiversity is acknowledged and prohibiting it would make the cost of

[24] Article 1 UPOV 1991
[25] Article 14 (1) UPOV 1991
[26] Article 15 (1) UPOV 1991
[27] Article 14 (1) UPOV 1991
[28] Unless it has been obtained through unauthorized use of propagating material
[29] On the compliance of the research exemption to the TRIPs Agreement, see the contribution of H. MORTEN HAUGEN: "Research Exemptions in Patent and Plant Variety Legislation".

inputs heavier for farmers[30]. It was partially preserved in the early versions of the UPOV Breeder's Right, as the authorization was not needed for farmer to reuse and exchange seeds. The 1991 version submits however the Farmers' Privilege to the adoption of an express exception by the member states. In the absence of such legal exception, farmers are not allowed to do so without the consent of the breeders.

The following countries have enacted a farmer's privilege in their plant variety protection system : Australia, Bulgaria (certain species only), Czech Republic (for certain crops only and a remuneration is due except for small farmers), Switzerland, European Union (for certain agricultural crops only and a remuneration is due except for small farmers), Estonia (a remuneration is due except for small farmers), Honk Kong (for certain varieties only), Japan (except as otherwise prescribed by contract), Lithuania (a remuneration is due except for small farmers) , Morocco, Thailand, US (only as to varieties protected by the Plant Variety Protection Act and for re-sowing only; no farmer's privilege if case of protection by Utility Patent Act or Plant Patent Act), Slovenia (a suitable remuneration to be paid, except small farmers). Such exemption is uncommon in Patent Right although some States have adopted it (the E.U. legislation has enacted such exemption to plant-related patent although an equitable remuneration is due to the right-holders, except for small farmers). The trend among breeders to deprive farmer from enjoying the farmers' privilege, by contractual or technical means, has been noted[31].

Next to the farmers' privilege and the breeder's right, it is worth noting the enactment by some national lawmakers of a compulsory license mechanism to the breeder's right. This aims at ensuring reasonable public access to the plant variety, in cases of absence of exploitation of the variety, insufficient offering for sale, or if access is not possible at reasonable prices (Australia, Hong Kong, Lithuania, Morocco, New Zealand, Thailand). Such flexibilities contrast with the strict rules that condition the adoption of compulsory licences to patent right according to TRIPs and the Paris Convention[32].

As a conclusion, the UPOV Convention appears much appropriate to satisfy the objective of balancing intellectual property with a sustainable realization of the right to food when compared to patent protection. The above-mentioned limitations to the Breeder's Right,

[30] See S.K. VERMA : "Right to Food and Intellectual Property Rights".
[31] Concerning technical and contractual limitations of the exceptions, see the contribution of D. BURK: "Contractual and Technical Restrictions of Patent Limitations" and S.K. VERMA : "Right to Food and Intellectual Property Rights: Farmers' Rights".
[32] See the contribution of M. BLAKENEY: "Compulsory Licensing and Food Security"

along with a narrower scope of protection, suggest such analysis. However, this must not conceal that the UPOV Convention has been conceived as an answer to the economic needs of the breeding industry from the North. This explains that the UPOV Convention, if appropriate to the business model of the latter, might remain unsatisfactory for the developing countries' agricultural activity and nutrition objectives. The substantial differences that distinguish the UPOV Convention with the *sui generis* PVP systems that were conceived in India and Africa[33] illustrate such assertion.

3. Flexibility possibilities

Along with the possible exemptions of plant, essentially biological processes and varieties from the scope of patent right, the TRIPs Agreement contains some other possibilities to customize the patent protection in order to balance it with conflicting social and economic goals such as the right to food. Those possibilities are just mentioned here as most of them will be further discussed in the present report.

3.1. Ordre public and morality, the protection of plant life and environment

The second paragraph of article 27 allows for exclusion from patentability[34] to protect "*ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment" . Experts are quite unanimous in favour of a narrow interpretation of this paragraph which would not allow states to exclude entire fields from patentability (such as biotech-agricultural or pharmaceutical products) but may only justify exclusions on a case-by-case basis[35].

[33] See the contribution of S.K.VERMA: "The TRIPs Flexibility Mechanisms and Right to Food" and the contribution of T. SANOU: "The alternative sui generis regimes as defended by the African group within the WTO: which protective system for the plant varieties?"

[34]" Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law".

[35] Dutfield (2004) citing Moufang (1998)

3.2. Exceptions and limitations

Article 30 provides members with the possibilities to establish *limited* exceptions to patent right provided that they *do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties*. Because of such conditions, the adoption of exception may be a limited tool to address food needs.

3.3. Compulsory licences

Article 31 allows for the adoption of compulsory licenses. However submitted to tight constraints, the compulsory licences option may in certain hypothesis offer a helpful means to accommodate the interest of the right-holders with nutrition needs in the context of the food crisis[36].

4. Conclusion

Although it establishes mandatory minimal standards of intellectual property protection, the TRIPs Agreement offers some limited breathing spaces for WTO members to craft their patent domain in accordance with social or economic conflicting needs. The possibility that states have to exclude plants and essentially biological processes for the production of plants from patentability is probably the most useful margin for them to address nutrition concerns. However member states have not taken much profit of this possibility nor of the discretion left to them to craft a sui generis protection variety system. The causes may be found on political or economic grounds.

The flexibilities given by the TRIPs must not conceal however that the globalization of intellectual property that the TRIPs Agreement conveys a major step in the extension of the North's set of social rules to the South. Before TRIPs, the extension on intellectual property to the living domain was rare. In addition, the integration of intellectual property among the concerns that require the care of the state, possibly placing it in conflict with other public concerns such as the right to food, is far from being trivial. In spite of the flexibilities granted by the Agreement, WTO member states have certainly lost means to address such public concerns. Interpreting the TRIPs (as many of its provisions are subject to interpretation) with

[36] See in the present report the contributions of M. BLAKENEY: "Compulsory Licensing and Food Security" and H. MORTEN HAUGEN: "Research exemptions in patent and plant variety legislation".

the criteria of preserving the public means to address policy concerns such as the right to sustainable food should therefore be recommended. Such interpretative compass is provided by Article 7[37] and 8[38], respectively titled “Objectives” and “Principles”.

[37] Article 7 TRIPs : « The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”

[38] Article 8.1 TRIPs : « Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement”.